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AUG 19 2003  
PATENT & TRADEMARK OFFICE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Castillo *et al.*  
Serial No.: 09/748,748  
Conf. No.: 4503  
Filed: December 26, 2000  
For: POLYHYDROXYLATED AROMATIC  
COMPOUNDS FOR THE  
TREATMENT OF AMYLOIDOSIS  
AND  $\alpha$ -SYNUCLEIN FIBRIL  
DISEASES  
Art Unit: 1614  
Examiner: Fay, Zohreh

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08/19/03  
Date

Michael Lough

TRANSMITTAL LETTER

Commissioner for Patents  
U.S. Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Transmitted herewith are a Supplemental Information Disclosure Statement; PTO-Form 1449 (6 pages); a check for \$180.00 and cited references for filing in connection with the above-identified application.

- [ X ] The Commissioner is hereby authorized to charge any fee, including any submitted herewith that may be due in connection with this and the attached papers, or with this application during its entire pendency to or to credit any overpayment to Deposit Account No. 50-1213. A duplicate of this sheet is enclosed.

Respectfully Submitted,  
Heller Ehrman White & McAuliffe LLP

*Dale L. Rieger*

Dale L. Rieger  
Registration No. 43,045

Attorney Docket No. 25835-4001  
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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN  
ACCORDANCE WITH 37 C.F.R. §§ 1.97(c)

Commissioner for Patents  
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P.O. Box 1450  
Alexandria, VA 22313-1450

08/25/2003 GWDRD0F1 00000030 09748748

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Dear Sir:

Since this Supplemental Information Disclosure Statement is filed after receipt of a first Office Action on the merits for the above-captioned application, the filing fee of \$180.00 is enclosed. If no proper payment is enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-1213.

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all references known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby provides this Supplemental Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§1.97-1.98.

Form PTO-1449 (6 pages) and copies of the cited documents are provided herewith, with the exception of items AK and BL, which will be provided under separate cover. The cited documents listed on Form PTO-1449 are supplied herewith in the English language, with the exception of item BB, which is in the German language. English language translation for item BB is being prepared and will be

**U.S.S.N. 09/748,748**  
**CASTILLO et al.**  
**Supplemental Information Disclosure Statement**

provided under separate cover. Hence, in accordance with the requirements of 37 C.F.R. §1.98, as amended effective March 16, 1992, no further explanation of the listed items is necessary.

Applicant also makes known to the Examiner the following U.S. and International applications, which are commonly owned and/or have one or more inventors in common.

<u>U.S.S.N.</u>	<u>Filing Date</u>	<u>Docket No.</u>
10/452,851	05/30/03	25835-4002
10/384,172	03/05/03	
09/036,492	03/06/98	
09/079,829	03/15/98	
09/497,628	02/03/00	
09/296,481	10/02/98	
09/525,787	03/15/00	

<u>Int'l App. No.</u>	<u>Filing Date</u>	<u>Docket No.</u>
PCT/US03/17288	5/30/03	25835-4002

Although these documents are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the references is effective as prior art against the subject application. In accordance with 37 C.F.R. §1.97(h), the filing of this Supplemental Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. §1.56(b) exists.

U.S.S.N. 09/748,748

CASTILLO et al.

**Supplemental Information Disclosure Statement**

Applicant respectfully requests that the Examiner review the foregoing references and that they be made of record in the file history of the above-captioned application.

Respectfully Submitted,  
Heller Ehrman White & McAuliffe LLP



Dale L. Rieger  
Registration No. 43,045

Attorney Docket No. 25835-4001

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FORM PTO-1449

LIST OF PATENTS AND PUBLICATIONS FOR  
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+ Derwent English language abstract and/or English translation provided.

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	*Ref. Code	DOCUMENT NUMBER							DATE	NAME	CLASS	SUB CLASS	FILING DATE
	A	0	0	1	3	6	4	8	01/16/03	Castillo <i>et al.</i>	514	12	09/24/01
	B	0	0	1	7	9	9	8	01/23/03	Snow <i>et al.</i>	514	27	02/15/02
	C	0	1	1	1	3	0	9	08/15/02	Castillo <i>et al.</i>	514	12	08/22/01
	D	0	1	9	7	6	9	2	12/26/02	Castillo <i>et al.</i>	435	184	11/02/01
	E	0	1	6	8	7	5	3	11/14/02	Castillo <i>et al.</i>	435	226	11/30/01
	F	5	6	4	3	5	6	2	07/01/97	Kisilevsky <i>et al.</i>	424	78.31	03/15/95
	G	5	6	8	1	5	6	9	10/28/97	Kuznicki <i>et al.</i>	424	195	11/06/95
	H	5	8	6	9	4	6	9	02/09/99	Szarek	514	120	08/18/97
	I	5	9	5	8	8	8	3	09/28/99	Snow	514	16	06/05/95
	J	5	9	7	2	9	5	6	10/26/99	Hays <i>et al.</i>	514	297	04/29/98
	K	5	9	8	1	1	6	8	11/09/99	Reiner	435	4	05/15/98
	L	6	0	3	7	3	2	7	03/14/00	Castillo <i>et al.</i>	514	23	08/28/98
	M	6	2	6	4	9	9	4	07/24/01	Castillo <i>et al.</i>	424	725	12/08/98
	N	6	3	4	0	7	8	3	01/22/02	Snow	800	12	10/03/96
	O	6	3	4	6	2	8	0	02/12/02	Castillo <i>et al.</i>	424	725	11/24/98
	P	6	4	3	2	6	3	6	08/13/02	Maresh <i>et al.</i>	435	6	08/26/97
	Q	6	5	6	3	0	1	6	05/13/02	Snow <i>et al.</i>	800	12	03/27/00

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	*Ref. Code	DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUB CLASS	Translation Yes No
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EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Title: **POLYHYDROXYLATED AROMATIC COMPOUNDS FOR THE TREATMENT OF AMYLOIDOSIS AND  $\alpha$ -SYNUCLEIN FIBRIL DISEASES**

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T	0	1	4	9	2	8	1	07/12/01	PCT				
U	0	1	4	9	3	0	7	07/12/01	PCT				
V	0	6	5	9	4	1	8	12/19/94	PCT				
W	1	0	1	4	9	9	6	05/28/03	EP				
X	9	7	4	6	6	6	4	12/11/97	PCT				
Y	9	8	0	8	3	8	1	03/05/98	PCT				
Z	9	8	3	9	6	5	3	09/11/98	PCT				
AA	9	8	5	1	3	0	2	11/19/98	PCT				

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

AB	Barner <i>et al.</i> , "Donepezil Use in Alzheimer Disease", <i>Ann. Pharmacotherapy</i> , 32:70-77 (1998)
AC	Benson <i>et al.</i> , "Serum Amyloid A Protein In Amyloidosis, Rheumatic, And Neoplastic Diseases", <i>Arth. Rheum.</i> , 22:36-42 (1979)
AD	Castillo <i>et al.</i> , "Laminin inhibition of beta-amyloid protein (A beta) fibrillogenesis and identification of an A beta binding site localized to the globular domain repeat on the laminin a chain", <i>J. Neurosci. Res.</i> , 62(3):451-462 (2000)
AE	Castillo <i>et al.</i> , "The sulfate moieties of glycosaminoglycans are critical for the enhancement beta-amyloid protein fibril formation", <i>J. Neurochem.</i> , 72(4):1681-1687 (1999)
AF	Castillo <i>et al.</i> , "Sulfate content and specific glycosaminoglycan backbone of perlecan are critical for perlecan's enhancement of islet amyloid polypeptide (amylin) fibril formation", <i>Diabetes</i> , 47(4):612-620 (1998)

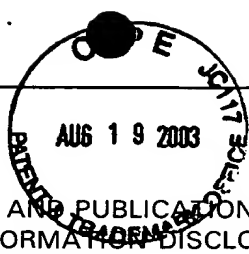
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FORM PTO-1449

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## OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

AG	Castillo <i>et al.</i> , "Perlecan binds to the beta-amyloid proteins (A beta) of Alzheimer's disease, accelerates A beta fibril formation, and maintains A beta fibril stability", <i>J. Neurochem.</i> , <u>69(6)</u> :2452-2465 (1997)
AH	Castillo <i>et al.</i> , "Novel purification and detailed characterization of perlecan isolated from the Engelbreth-Holm-Swarm tumor for use in an animal model of fibrillar A beta amyloid persistence in brain", <i>J. Biochem.</i> , <u>120(2)</u> :433-444 (1996)
AI	Castillo <i>et al.</i> , "Subunit structure of bovine ESF (extracellular-matrix stabilizing factor(s)). A chondroitin sulfate proteoglycan with homology to human I alpha i (inter-alp trypsin inhibitors)", <i>FEBS Lett.</i> , <u>318(3)</u> :292-296 (1993)
AJ	Castillo <i>et al.</i> , "Structure and metabolism of multiple heparan sulphate proteoglycans synthesized by the isolated rat glomerulus", <i>Biochem. Biophys. Acta</i> , <u>1136(2)</u> :119-128 (1992)
AK	Crutcher <i>et al.</i> , "Cellular and molecular pathology in Alzheimer's disease", <i>Hippocampus</i> , <u>3</u> :271-287 (1993)
AL	Cutler <i>et al.</i> , "Tacrine in Alzheimer's Disease", <i>N. Engl. J. Med.</i> , <u>328</u> :808-810 (1993)
+AM	Derwent WPI Acc. No. 12134240 (citing Japanese Patent 10245342 A), "Agent for reducing the nerve cell toxicity of beta-amyloid protein containing tea polyphenol is new"
AN	Fraser <i>et al.</i> , "Conformation and fibrillogenesis of Alzheimer A beta peptides with selected substitution of charged residues", <i>J. Mol. Biol.</i> , <u>244(1)</u> :64-73 (1994)
AO	Fukuchi <i>et al.</i> , "Increased expression of beta-amyloid protein precursor and microtubule-associated protein tau during the differentiation of murine embryonal carcinoma cells", <i>J. Neurochem.</i> , <u>58(5)</u> :1863-1873 (1992)
AP	Geyjo <i>et al.</i> , " $\beta_2$ -microglobulin: A new form of amyloid protein associated with chronic hemodialysis", <i>Kidney Int.</i> , <u>30</u> :385-390 (1986)
AQ	Geyjo <i>et al.</i> , "A New Form of Amyloid Protein Associated with Chronic Hemodialysis was Identified as $\beta_2$ -microglobulin", <i>Biochem. Biophys. Res. Comm.</i> , <u>129</u> :701-706 (1985)

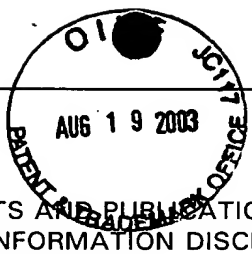
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## OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

AR	Grundke-Ibal <i>et al.</i> , "Abnormal phosphorylation of the microtubule-associated protein tau in alzheimer cytoskeletal pathology", <i>Proc. Natl. Acad. Sci. USA</i> , <u>83</u> :4913-4917 (1986)
AS	Harada <i>et al.</i> , "Human Amyloid Protein: Chemical Variability And Homogeneity", <i>J. Histochem. Cytochem.</i> , <u>19</u> :1-15 (1971)
AT	Hardy <i>et al.</i> , "Framing $\beta$ -amyloid", <i>Nature Genet.</i> , <u>1</u> :233-234 (1992)
AU	Hart <i>et al.</i> , "Overproduction of perlecan core protein in cultured cells and transgenic mice", <i>J. Pathol.</i> , <u>194</u> (2):262-269 (2001)
AV	Johnson <i>et al.</i> , "Biology of Disease. Islet Amyloid Polypeptide: Mechanisms of Amyloidogenesis in the Pancreatic Islets and Potential Roles in Diabetes Mellitus", <i>Lab. Invest.</i> , <u>66</u> :522-535 (1992)
AW	Johnson <i>et al.</i> , "Islet Amyloid, Islet-Amyloid Polypeptide, and Diabetes Mellitus", <i>N. Engl. J. Med.</i> , <u>321</u> :513-518 (1989)
AX	Jucker <i>et al.</i> , "Age-related deposition of glia-associated fibrillar material in brains of C57BL/6 mice", <i>Neuroscience</i> , <u>60</u> (4):875-889 (1994)
AY	Kamei <i>et al.</i> , "Amyloidosis Associated With Juvenile Rheumatoid Arthritis", <i>Acta Path. Jpn.</i> , <u>32</u> :123-133 (1982)
AZ	Kosik <i>et al.</i> , "Microtubule-associated protein tau is a major antigenic component of paired helical filaments in Alzheimer disease", <i>Proc. Natl. Acad. Sci. USA</i> , <u>83</u> :4044-4048 (1986)
BA	Lee <i>et al.</i> , "A68: A Major Subunit of Paired Helical Filaments and Derivatized Forms of Normal Tau", <i>Science</i> , <u>251</u> :675-678 (1991)
BB	Lewy in <i>Handbuch der Neurologie</i> , Lewandowski, Ed., Springer, Berlin, pp. 920-933, 1912
BC	Maresh <i>et al.</i> , "Detection and quantitation of perlecan mRNA levels in Alzheimer's disease a normal aged hippocampus by competitive reverse transcription-polymerase chain reaction", <i>J. Neurochem.</i> , <u>67</u> (3):1132-1144 (1996)
BD	McAdam <i>et al.</i> , "Association of Amyloidosis with Erythema Nodosum Leprosum Reactions and Recurrent neutrophil Leucocytosis in Leprosy", <i>Lancet</i> , <u>2</u> :572-573 (1975)

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OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

BE	Miller <i>et al.</i> , "Localization of perlecan (or a perlecan-related macromolecule) to isolated microglia in vitro and to microglia/macrophages following infusion of beta-amyloid protein into rodent hippocampus", <i>Gila</i> , <u>21(2)</u> :228-243 (1997)
BF	Metaxas <i>et al.</i> , "Familial Mediterranean fever and amyloidosis", <i>Kidney Int.</i> , <u>20</u> :676-685 (1981)
BG	Rogers <i>et al.</i> , "Long-term efficacy and safety of donepezil in the treatment of Alzheimer's disease: an interim analysis of the results of a US multicentre open label extension study", <i>Eur. Neuropsychopharmacol.</i> , <u>8</u> :67-75 (1998)
BH	Saraiva <i>et al.</i> , "Amyloid Fibril Protein in Familial Amyloidotic Polyneuropathy, Portuguese Type", <i>J. Clin. Invest.</i> , <u>74</u> :104-119 (1984)
BI	Saraiva <i>et al.</i> , "Studies on plasma transthyretin (prealbumin) in familial amyloidotic polyneuropathy, Portuguese type", <i>J. Lab. Clin. Med.</i> , <u>102</u> :590-603 (1983)
BJ	Sekiguchi <i>et al.</i> , "Characterization of proteoglycans synthesized by murine embryonal carcinoma cells (P19) reveals increased expression of perlecan (heparan sulfate proteoglycan) during neuronal differentiation", <i>J. Neurosci. Res.</i> , <u>38(6)</u> :670-686 (1994)
BK	Skinner <i>et al.</i> , "The Prealbumin Nature of the Amyloid Protein in Familial Amyloid Polyneuropathy (FAP)-Swedish Variety", <i>Biochem. Biophys. Res. Comm.</i> , <u>99</u> :1326-1332 (1981)
BL	Snow <i>et al.</i> , "In vitro and in vivo models to unravel the potential roles of beta/A4 in the pathogenesis of Alzheimer's disease", <i>Hippocampus</i> , <u>3</u> :257-267 (1993)
BM	Snow <i>et al.</i> , "An important role of heparan sulfate proteoglycan (Perlecan) in a model system for the deposition and persistence of fibrillar A beta-amyloid in rat brain", <i>Neuron</i> , <u>12(1)</u> :219-234 (1994)
BN	Snow <i>et al.</i> , "Peripheral distribution of dermatan sulfate proteoglycans (decorin) in amyloid containing plaques and their presence in neurofibrillary tangles of Alzheimer's disease", <i>J. Histochem Cytochem.</i> , <u>40(1)</u> :105-113 (1992)
BO	Snow <i>et al.</i> , "Identification in immunolocalization of a new class of proteoglycan (keratan sulfate) to the neuritic plaques of Alzheimer's disease", <i>Exp. Neurol.</i> , <u>138(2)</u> :305-317 (1996)

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#### OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

BP	Snow <i>et al.</i> , "Differential binding of vascular cell-derived proteoglycans (perlecan, bigly decorin, and versican) to the beta-amyloid protein of Alzheimer's disease", <i>Arch. Biochem. Biophys.</i> , <u>320</u> (1):84-95 (1995)
BQ	Snow <i>et al.</i> , "Heparan sulfate proteoglycan in diffuse plaques of hippocampus but not of cerebellum in Alzheimer's disease brain", <i>Am. J. Pathol.</i> , <u>144</u> (2):337-347 (1994)
BR	Tawara <i>et al.</i> , "Amyloid fibril protein in type I familial amyloidotic polyneuropathy in Japanese", <i>J. Lab. Clin. Med.</i> , <u>98</u> :811-822 (1989)

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Title: **POLYHYDROXYLATED AROMATIC COMPOUNDS FOR THE TREATMENT OF AMYLOIDOSIS AND  $\alpha$ -SYNUCLEIN FIBRIL DISEASES**